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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/819,157	03/27/2001	Jonathan L. Coffman	01997.024800	2662

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EXAMINER

SNEDDEN, SHERIDAN

ART UNIT PAPER NUMBER

1653

DATE MAILED: 12/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/819,157

Applicant(s)

COFFMAN ET AL.

Examiner

Sheridan K Snedden

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 29 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 36-45 is/are allowed.
- 6) ☒ Claim(s) 46 and 50-53 is/are rejected.
- 7) ☐ Claim(s) 47-49 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Response to Amendment

1. This Office Action is in response to Paper filed 29 April 2004. Claims 1-35 have been canceled. Applicant's amendment of claims 36, 42 and 46 is acknowledged. Claims 36-51 are under examination.

Withdrawal of Objections and Rejections

2. Applicant has cancelled all previous pending claims, therefore, all objections and/or rejections are withdrawn.

Maintained Rejections

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 46 and 50-52 are rejected under 35 U.S.C. 102(b) as being anticipated by Burton *et al.* (6,423,831). Burton *et al.* teach the purification of neurotrophin and neurotrophin variants using hydrophobic interaction chromatography. Burton *et al.* teaches that the column is loaded with sample and that the loading sample preferably contains 2.5 M NaCl. Burton *et al.* additionally teach that 10% alcohol is added to the solution for elution. Thus, the reference anticipates the claimed invention.

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Applicant's argue that the above reference does not teach the purification of anionic proteins. In response, the rejection as it applies to claim 47 is withdrawn. The remaining claims 46 and 50-51 do not recite a limitation requiring the purification of anionic proteins solely.

Applicant's argue that the above reference teaches an additional step for the removal of DNA, prior to the HIC step, and as such teaches an additional step. This argument is considered but is not persuasive. The method as claimed does not exclude additional steps. Furthermore, this argument rest on the intended use for the process step. What is relevant to the present analysis is that the same method step is taught and would be capable of performing the intended use, which is to remove DNA from the sample. As the reference teaches a method of protein purification, removal of DNA from the sample is inherent.

New Rejections/ Objections

Claim Objections

Claims 47-49 are objected to because of the following informalities: the claims are dependent on rejected claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 46 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burton *et al.* (6,423,831). Burton *et al.* teach the purification of neurotrophin and neurotrophin variants using hydrophobic interaction chromatography. Burton *et al.* teaches that the column is loaded with sample and that the loading sample preferably contains 2.5 M NaCl. Burton *et al.* additionally teach that 10% alcohol is added to the solution for elution. It is an arbitrary design choice to choose purification by column or batch. Thus, it would have been obvious to the person of ordinary skill in the art at the time the invention was made to perform the method of purification in batch form. Thus, the claimed invention was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious.

Conclusion

5. Claims 36-45 are in condition for allowance.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

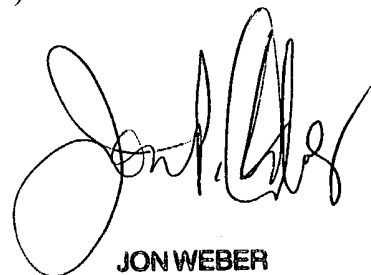
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan K Snedden whose telephone number is (571) 272-0959. The examiner can normally be reached on Monday - Friday, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for regular communications to the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SKS
November 29, 2004

SKS

A handwritten signature in black ink, appearing to read "Jon Weber", with a large, stylized initial "J" and "W".

JON WEBER
SUPERVISORY PATENT EXAMINER